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| 10/699,295      | 10/31/2003  | Hikmat Hojeibane     | CRD-5051            | 2568             |

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| EXAMINER |
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PELLEGRINO, BRIAN E

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

3738

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 02/13/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/699,295

Applicant(s)

HOJEIBANE ET AL.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 23,25,26,30 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22,24,27-29,32 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3,5,6,8,9,22,24,27,28,29,32,33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pavcnik et al. (6200336) in view of Pinheiro (6355056). Fig. 18 shows an expandable anchor having a cylindrical shape and a lattice structure **30,31** interconnected by outer tubular member 64. Fig. 17 shows a collar **15** used to attach the anchor structure to a straight connecting member **16** that extends longitudinally to fasten with a cantilever valve strut **11** with a free end to deflect radially from the longitudinal axis. It can also be seen there is a biocompatible membrane **45** having a "substantially tubular" configuration about the longitudinal axis. Pavcnik discloses the frame can be made of stainless steel or nickel-titanium, col. 3, lines 17-19. Pavcnik also discloses the membrane is formed of a biological material or synthetic fabric, col. 5, lines 31-33. The "substantially tubular" membrane can be construed as having a "substantially conical shape." However, Pavcnik et al. fail to disclose attachment of the connecting member to the second end of the anchor structure. Pinheiro teaches (Fig. 1) attachment of a connecting member 40 at the second end of anchoring structure. Pinheiro also teaches that attaching at the second end ensures the distance remains the same between the ends and prevents migration of the structure, col. 5, lines 17-21. It would have been obvious to one of ordinary skill in the art to place the connecting

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member at the second end of the anchor structure as taught by Pinheiro with the prosthetic valve device of Pavcnik et al. such that it ensures it will not migrate. With respect to claim 27, it would have been an obvious matter of design choice to modify the diameter of the membrane, since applicant has not disclosed that using a "substantially constant diameter" provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the profile of the membrane taught by Pavcnik et al. or the claimed "substantially constant diameter" profile in claim(s) 27 because both membranes perform the same function of controlling blood flow.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pavcnik et al. '336 in view of Pinheiro '056 and further in view of Quijano et al. (5500014). Pavcnik et al. as modified by Pinheiro is explained supra. However, Pavcnik in view of Pinheiro do not disclose the use of biological vein material for the membrane. Quijano et al. teach that venous graft material is used in prosthetic valve devices (col. 6, lines 6,7) and that tanning the material provides certain stiffness properties, col. 11, lines 22-25. It would have been obvious to one of ordinary skill in the art to use venous material as taught by Quijano et al. for the membrane of Pavcnik et al. such that it provides a natural biological material that is sufficient to withstand the pressure of the blood flow in the patient since it is a natural material.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pavcnik et al. '336 in view of Pinheiro '056 and further in view of Konya et al. (6368338).

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Pavcnik et al. as modified by Pinheiro is explained supra. However, Pavcnik in view of Pinheiro fail to disclose the membrane material comprises a reinforcement fiber. Konya shows (Fig. 1) a filtering device. Konya also teaches that the filtering device can include reinforcement or structural fibers, col. 12, lines 23-31. It would have been obvious to one of ordinary skill in the art to use reinforcement fibers as taught by Konya with the membrane of Pavcnik in view of Pinheiro such that it strengthens the apparatus and prevents collapse.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pavcnik et al. '336 in view of Pinheiro '056 and further in view of Huter et al. (6511496). Pavcnik et al. as modified by Pinheiro is explained as before. However, Pavcnik in view of Pinheiro fail to disclose the structural frame is made of a polymer. Huter discloses the structural frame may be made of polymers, col. 4, lines 2-4. It would have been obvious to one of ordinary skill in the art to substitute materials and use a polymer for the frame or anchor as taught by Huter et al. for the device of Pavcnik et al. in view of Pinheiro such that it provides a lighter device for delivery.

Claims 10,12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pavcnik et al. '336 in view of Pinheiro '056 and further in view of Alt et al. (5788979). Pavcnik et al. as modified by Pinheiro is explained as before. However, Pavcnik in view of Pinheiro fail to disclose the structural frame or the membrane is coated with a therapeutic agent. Alt et al. teach that biodegradable polymer materials can be loaded with drugs or pharmaceutical agents (col. 4, lines 14-29) to treat an area where a prosthesis (col. 8, lines 57-60) is implanted. It would have been obvious to one of

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ordinary skill in the art to use a biodegradable polymer with a drug as taught by Pavcnik et al. as modified by Pinheiro with the device of Alt et al. such that it prevents restenosis or thrombosis from occurring.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1,32,33 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-F (9am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

**BRIAN E. PELLEGRINO**  
**PRIMARY EXAMINER**

*Brian E Pellegrino*